

3. Analysis of Substantive rejections.

Rejections pursuant to 35 USC Section 112.

The applicant has amended Claims 32-34, 37 & 39 to correct claim indefiniteness.

Rejections pursuant to 35 USC Section 102(e). The USPTO rejected Claims 29 - 34 under 35 USC Section 102(e) as being anticipated by David Ginsburg Primary Psychiatry, PP 17-20, 8(6), 2001. If the applicant's assertion that the effective filing date of the application is March 29, 1999, then this rejection must be withdrawn as this reference was not published until 2001. Because of the previous arguments which establish an effective filing date of the application of March 29, 1999, the applicant requests that this rejection be withdrawn.

Claims 29 - 39 were also rejected under 35 USC Section 102(e) as being anticipated by Jane Todd et al, WO 00/74784. The publication date of this reference is December 14, 2000. If the "effective" filing date of this application is accepted as being March 29, 1999, then this reference must also be withdrawn as it was published after that date.

The applicant respectfully reserves the right to discuss and distinguish the specific disclosures of each of these references, but does not believe that any additional discussion is necessary at this time as these references should be withdrawn based on the effective filing date of the application.

Rejection under 35 USC §§ 102 and 103 based on Rosenberg, U.S. Patent No. 5,897,910 in view of Deutsch et al.

The USPTO rejected all claims of the application based on these references. (Notwithstanding, the Examiner stated by conference call that the rejection should also have been based on 35 USC Section 102 and that Deutsch et. al. anticipates the method claims.) The applicant respectfully traverses this rejection.

The applicant asserts that Deutsch et. al. merely teaches the therapeutic benefits of adding a histamine H<sub>2</sub> antagonist, such as famotidine, as an adjunctive medication to antipsychotic drugs to directly treat schizophrenic patients for their mental illnesses. This conclusion was acknowledged specifically on page 7, lines 7-10 of the Office Action. In contrast to this teaching, there is no disclosure in Deutsch et. al. of the use of this drug combination as a means of preventing or reducing weight gain.

It is important to note that each claim of the application is a "method" claim. Deutsch, et. al. fails to disclose a method for reducing weight gain when taking such medication. Moreover, Deutsch et. al. do not disclose the use of these drugs as an adjunctive to mood altering drugs. In addition, Deutsch et. al. do not disclose the claimed compositions involving a combination of drugs administered simultaneously. (The combination of Deutsch et. al. with Rosenberg will be discussed in the next section of this Response.)

The USPTO has asserted that Rosenberg et. al. "teaches processes of making tablets comprising one or more active ingredients wherein such active ingredients may be selected from antipsychotics... mood stabilizing agents ... and histamine H<sub>2</sub> antagonist...." (Para. 8) Notwithstanding, the Examiner acknowledges that Rosenberg et. al. fail to teach a weight loss method from the combination of an antipsychotic agent with an H<sub>2</sub> antagonist.

Rosenberg et. al. merely teach a process that has nothing to do with the treatment of weight gain induced by psychoactive agents. In contrast to the method of the claims of the application, Rosenberg et. al. merely discloses "a process for the production of covered tablet by melt calendering in which the melt containing active ingredients are introduced between two sheets of the covered material into the molding rolls." Thus, the process of Rosenberg et. al. is mixing an active ingredient of a drug "in one or more conventional ancillary substances" to produce drug blends using a particular processes. While Rosenberg et. al. mentions a number of antipsychotics, mood stabilizing agents and histamine H<sub>2</sub> antagonist as possible drugs for use, these are merely mentioned in a list containing literally hundreds of active ingredients. There is no recognition that the choice of the three particular types of materials should be put together under any circumstance and in particular for the treatment of weight gain.

## LEGAL ANALYSIS

In order for a reference to teach an invention, it is necessary that the reference disclose the invention to a person skilled in the art. Nothing in Rosenberg et. al. alone or its combination with Deutsch et. al. would teach a person skilled in the art a method to avoid weight gain by combining two of these particular types of drugs. In fact, nothing in these references teaches anything about methods for preventing weight gain, or even the combination of these particular drugs for any method. Accordingly, this invention is simply not taught to a person skilled in the art.

In addition, the combination of these references under 35 USC Section 103 is also not permitted. To reject a claim under 35 USC Section 103, the USPTO must establish a *prima facie* case of obviousness. At best the USPTO has established, through hindsight, that it might be "obvious to try" a combination of certain drugs. However, even if an "obvious to try" standard exists, which it does not, there is clearly no teaching that the combination of these references would be useful as a method for weight control.

Obviousness cannot be established by combining the teaching of the prior art to produce the claimed invention absent some teaching, suggestion, or incentive supporting the combination. (*In re: Kiger* 2 USPQ 2nd 1276, 1278 (CAFC 1987)).

At best, one skilled in the art might find it obvious to try

various combination of these drugs for psychiatric uses. However, that is not the standard under 35 USC Section 103. *In re Goodwin*, 576 Fd. 2nd 375, 377 (CCPA 1978); *In re Antonie* 559 Fd. 2nd 618 (CCPA 1977).

The Examiner has asserted that "the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." (Office Action, page 8) Such an argument might have validity if the applicant was attempting to claim the combination of these drugs for all use. In contrast, the claims are method claims claiming "a method for minimizing weight gain in a patient taking a psychotropic active compound..." This method is not even mentioned in any of the references cited.

To establish a "*prima facie*" case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Clearly no such suggestion is present as neither reference even mentions the use of these drugs for weight control.

The second criteria necessary to establish "*prima facie*" obviousness is a reasonable expectation of success to meet the method of the claim. There cannot be any such reasonable

expectation of reducing weight when the problem in using these types of drugs has been weight gain, not weight loss. Thus, all of the art that has been present has shown that taking certain psychotropic drugs results in weight gain, not weight loss. Thus, there is no "reasonable expectation of success."

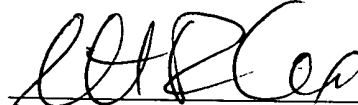
Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. This criteria is also not satisfied as the combination of these particular drugs for this particular method is not even contemplated by these references.

Because no element of a *prima facie* showing of obviousness is present, and certainly not any showing that such combination would produce a drug that would be useful to prevent weight gain, Rosenberg et. al. alone or in combination with Deutsch et. al. fail to disclose the invention, as claimed.

Conclusion

The applicant asserts that the rejections and objections have been overcome and requests that a Notice of Allowance be issued. If there is any questions concerning this matter, please contact applicant's counsel.

Respectfully submitted,



Scott R. Cox

Reg. No. 31,945

LYNCH, COX, GILMAN & MAHAN, P.S.C.

400 West Market Street, Suite 2200

Louisville, Kentucky 40202

(502) 589-4215

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Dated: December 19, 2003 Nelly Hart

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